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REMARKS

Claims 1- 21 were presented when the instant application was filed. Subsequently, in a response to a restriction requirement, Applicants elected to prosecute Claims 1-15 of Group I, and canceled Claims 16-21 without prejudice to their future prosecution. Thus Claims 1-15 are currently pending. In the instant Office Action, the Examiner has raised a number of issues which are set forth by number in the order they are herein addressed:

1) the Information Disclosure Statement filed July 2, 2003, is objected to for allegedly listing missing or incomplete references (nos. 33, and 40-55 on Form PTO-1449);

2) the Specification and Title are objected to for alleged failure to capitalize trademarks and as allegedly not descriptive of the claimed methods;

3) the Declaration is objected to for allegedly containing identification and priority defects;

4) Claims 1 and 9 are objected to for allegedly containing informalities;

5) Claims 1-15 are rejected under 35 USC § 112, second paragraph, as allegedly being indefinite;

6) Claims 1-15 are rejected under 35 USC § 102(e) as allegedly being anticipated by Strauss (US Publication No. 2002/0086289 A1) as evidenced by DeRisi *et al.* (Science 278:680-686, 1997).

Applicants hereby amend Claims 1 and 9, in order to further the prosecution of the present application and Applicants' business interests, yet without acquiescing to the Examiner's arguments. Applicants reserve the right to prosecute the original, similar, or broader Claims in one or more future application(s). These amendments do not introduce new matter and are not intended to narrow the scope of any of the claims within the meaning of *Festo*.[1]

1) Information Disclosure Statement Clarification

The Examiner has objected to the Information Disclosure Statement (IDS) for allegedly listing missing or incomplete references (nos. 33, and 40-55 on Form PTO-1449).

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[1] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 122 S.Ct. 1831, 1838, 62 USPQ2d 1705, 1710 (2002).

Applicants thank the Examiner for completing the references listed as nos. 40-43 on Form PTO-1449, and for consideration of the references listed as nos. 1-32, 34-43, and 56-71 on Form PTO-1449. Applicants included the bacterial strain product information sheets (cited in the Specification and listed as nos. 44-55 on Form PTO-1449) in the IDS and obtained from the ATCC Internet site, for the sake of completeness.

2) The Specification and Title Are Proper

The Examiner has objected to the Specification and Title for alleged failure to capitalize trademarks and as allegedly not descriptive of the claimed methods. Applicants have amended the Title and Specification as shown herein beginning on page 2. Applicants believe that the amendments are sufficient to overcome the Examiner's objections.

3) The Substitute Declaration is Proper

The Examiner has objected to the declaration for allegedly failing to adequately identify the instant application and for including an improper priority claim. Applicants thank the Examiner for drawing their attention to these typographical errors. Accordingly, Applicants have executed a substitute Declaration (attached hereto at Tab 1), which lists the serial number and filing date of the instant application, and which includes a claim under 119(e) instead of 120 to the parent provisional application.

4) The Claims Are Proper

The Examiner has objected to Claims 1 and 9 for reference to "a test bacteria" rather than either "a test bacterium" or "test bacteria" (Office Action, page 4). As suggested by the Examiner, Applicants have amended Claims 1 and 9 to recite simply "test bacteria."

5) The Claims Are Definite

The Examiner has rejected Claims 1-15 under 35 U.S.C. §112, second paragraph as allegedly being indefinite. In the first place, the Examiner states:

> Claims 1-8 are indefinite over the recitation of the phrase 'labeled reference DNA from at least four strains of bacteria represented on said solid support' in claim 1. It is unclear as to whether this language requires that 'labeled reference DNA from at least four strains of bacteria' be present on 'said solid

> support,' or whether the claims require a solid support comprising 'amplified genomic sequences' from at least four strains of bacteria, as well as 'labeled reference DNA' from at least four of these strains in some other form (e.g., in solution) (Office Action, page 4).

A similar rejection of Claims 9-15 has been lodged by the Examiner. Applicants respectfully disagree that the claims are indefinite. Nonetheless, Applicants have amended Claims 1 and 9, in order to further the prosecution of the present application and Applicants' business interests, yet without acquiescing to the Examiner's arguments, and while reserving the right to prosecute the original, similar, or broader claims in one or more future application(s). Specifically, Applicants have amended Claims 1 and 9 to recite "wherein said amplified genomic sequences are arrayed on a solid support/microchip" and to recite "labeled reference DNA from at least four strains of reference bacteria, wherein said reference bacteria are members of the group consisting of said plurality of bacterial species" in step a. The amendments to the claims, in combination with the teaching of Example 2, clearly indicate that the labeled reference DNA is not arrayed on the solid support/microchip.

Secondly, the Examiner states:

> Claims 1-8 are indefinite over the recitation of the limitation 'said arrayed sequences' in claim 1. While the claim previously refers to 'amplified genomic sequences' and to a 'plurality of arrayed elements,' the claim does not previously recite the term 'arrayed sequences (Office Action, page 4).

A similar rejection of Claims 9-15 has been lodged by the Examiner. Applicants respectfully disagree that the claims are indefinite. Nonetheless, Applicants have amended Claims 1 and 9, in order to further the prosecution of the present application and Applicants' business interests, yet without acquiescing to the Examiner's arguments, and while reserving the right to prosecute the original, similar, or broader claims in one or more future application(s). Specifically, Applicants have amended Claims 1 and 9 to recite "arrayed elements" in step b.

In addition, the Examiner states:

> Claims 1-8 are indefinite over the recitation of the phrase 'calculating the hybridization signal intensity ratio at each array element to determine the identity of said test bacteria' in claim 1. It is noted that the claim as written encompasses, e.g., the use of identically labeled target and reference DNA, target and reference DNAs hybridized to either the same or different solid supports, etc. The specification described the calculation of 'Hybridization signal ratios *(R)* between test and reference DNA' (page 34), and provides a definition at page 17 for the term 'signal to noise ratio' which states that such a

> ratio is 'computed by taking the ratio of levels of the desired signal to the level of noise present within the signal.' However, the specification does not provide any type of limiting definition for the term 'hybridization signal intensity ratio,' and the claims do not indicate what signals are compared to obtain such a ratio. Accordingly, it is unclear as to what type of calculation or calculations is/are actually encompassed by this recitation in the claims, as well as to how such calculation(s) allow one 'to determine the identity of said test bacteria' (Office Action, page 5).

A similar rejection of Claims 9-15 has been lodged by the Examiner. Applicants respectfully disagree that the claims are indefinite. Nonetheless, Applicants have amended Claims 1 and 9, in order to further the prosecution of the present application and Applicants' business interests, yet without acquiescing to the Examiner's arguments, and while reserving the right to prosecute the original, similar, or broader claims in one or more future application(s). Specifically, Applicants have amended Claims 1 and 9 to recite "wherein each hybridized target DNA in said hybridization pattern has a target signal, and each hybridized reference DNA in said hybridization pattern has a reference signal" and "calculating the target signal to reference signal hybridization ratio" in steps b and c.

Lastly, the Examiner states:

> Claim 8 is indefinite over the recitation of the limitation 'said test and reference bacteria.' While claim 1 refers to 'test bacteria,' there is insufficient antecedent basis for 'reference bacteria' in the claims (Office Action, page 5).

A similar rejection of Claim 13 has been lodged by the Examiner. Applicants respectfully disagree that the claims are indefinite. Nonetheless, Applicants have amended Claims 1 and 9, in order to further the prosecution of the present application and Applicants' business interests, yet without acquiescing to the Examiner's arguments, and while reserving the right to prosecute the original, similar, or broader claims in one or more future application(s). Specifically, Applicants have amended Claims 1 and 9 to recite "reference bacteria" in step b.

Support for the above amendments is found for instance in the Summary which teaches "[g]enomic DNA from test strains...is labeled by random priming, and co-hybridized to the chip with reference DNA, which is a mixture of genomic DNAs from the multiple references species (strains). The hybridized chips are then laser scanned, and a hybridization ratio (test DNA/reference DNA) for each spot on the array is determined" (Specification, at page 6, lines 22-27). As such the amendments to the claims do not add new matter, but

simply rephrase existing text. As the amended claims are definite, Applicants respectfully request that this rejection be withdrawn.

6) The Claims Are Novel

The Examiner has rejected Claims 1-15 under 35 U.S.C. §102(e), as allegedly being anticipated by Strauss (US Publication No. 2002/0086289 A1) as evidenced by DeRisi *et al.* (Science 278:680-686, 1997). Specifically the Examiner states:

> "Straus discloses a method for identifying bacteria in which labeled target DNA from a test sample including bacteria is hybridized to a 'detection ensemble' of detection sequences from 5 or more distinct genomes arrayed on a solid support (see entire reference, particular pages 3-4 and the definition of 'minimum genomic derivation' at pages 7-8). Straus teaches that in embodiments of his invention, the detection sequences arrayed on a solid support are amplified genomic DNAs (see, e.g., page 17, right column). Straus further discloses both the combination of positive and negative control probes with test sample molecules prior to hybridization (see, e.g., page 19), and preparation of a database of fingerprints with which test sample patterns may be compared (see, e.g., page 28). Regarding the step of 'calculating hybridization signal intensity ratio at each array element,' it is noted that Straus states that "Microarrays are scanned with a laser fluorescent scanner, and signals are processed and recorded as is described in published reports,' referring to the DeRisi et al reference (page 25). The DeRisi et al reference discloses that processing and recording of signals comprises calculation of a hybridization signal intensity ratio (see entire reference, particularly footnote 49). Accordingly, it is an inherent property of the method disclosed by Straus that it includes such a step, and therefore Straus anticipates the instant claims.
>
> Regarding claims 5 and 9-15, it is further noted that the solid supports disclosed by Straus include microchips (see, e.g., page 10). Regarding claims 2-4 and 10-12, it is noted that the samples disclosed by Straus include samples from a test subject, samples comprising pathogens, and environmental samples (see pages 4, 10, and 12). Regarding claim 6, the processing disclosed by DeRisi et al comprises statistical analysis (see footnote 49 of DeRisi et al)" (Office Action, pages 7 and 8).

Applicants must respectfully disagree. Nonetheless, Applicants have amended Claims 1 and 9, in order to further the prosecution of the present application and Applicants' business interests, yet without acquiescing to the Examiner's arguments, and while reserving the right to prosecute the original, similar, or broader claims in one or more future application(s). Specifically, Applicants have amended Claims 1 and 9 to recite "co-hybridizing said target

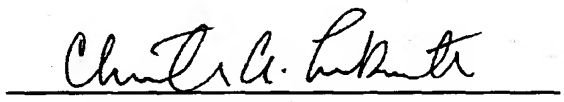
and reference DNA to said arrayed elements" in step b. As discussed in part 5 above, support for this amendment is found in the summary of the application as filed.

The Examiner is respectfully reminded that a "claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."[2] In contrast to the claimed invention, Straus does not teach or suggest "co-hybridizing said target and reference DNA to said array elements." As shown in Figure 5, Straus teaches hybridization of probe-halves to target DNA attached to a solid support, to select a subset of the probe molecules for *subsequent* amplification, labeling and hybridization to a detection array. Thus, the two separate hybridization steps of Straus are clearly distinct from the single co-hybridization step recited in amended Claims 1 and 9. As Straus does not anticipate the amended claims, Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

Applicants believe the amendments and arguments set forth above traverse the Examiner's rejections and, therefore, request that a timely Notice of Allowance be issued in this case. However, should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned collect.

Dated: March 1, 2004



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[2] *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).